

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Rush E. Simonson

Application No.: 10/696,727

Filed: October 28, 2003

For: VERTEBRAL IMPLANTS
ADAPTED FOR POSTERIOR
INSERTION

Customer No.: 20350

Confirmation No. 6338

Examiner: Michael J. Araj

Technology Center/Art Unit: 3732

DECLARATION OF
WILLIAM A. BRENNAN M.D., F.A.C.S.
[37 C.F.R. § 1.132]

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, William A. Brennan, M.D., F.A.C.S., declare as follow:

1. I am a neurosurgeon who has been certified by the American Board of Neurological Surgery in May, 2000. I received my M.D. degree from the University of South Carolina School of Medicine in May, 1988. I then became a general surgery intern at Vanderbilt University Medical Center from July 1988 to June 1989. Afterward, I had a neurosurgery residency at Vanderbilt University Medical School from July 1989 to June 1995. Following my residency, I have been in private surgical practice at Commonwealth Neurosurgery Ltd. (August 1995 - February 1996), Larry Fishman M.D., P.A. (June 1996- June 1997) and Neurology and Neurosurgery Associates P.A. (July, 1997 to December, 2004). In am presently participating in a Cosmetic Surgery Fellowship at Inland Cosmetic Surgery in California.

2. As part of my neurosurgery practice, I have performed over a two thousand spinal surgeries, including vertebral fusions and disc replacement surgeries. I have

used both anterior and posterior methods for my spinal surgeries. As a result of my medical training and extensive spinal surgery experience, I am familiar with technical issues involved in different types of spinal surgeries.

3. I have reviewed Mr. Rush Simonson's U.S. Patent Application No. 10/696,727 and its presently pending claims. I have been asked by Mr. Simonson to provide my opinion about whether the posterior spinal disc replacement surgery approach described in Mr. Simonson's presently pending claims would be patentably distinct from the anterior spinal disc replacement surgery approaches now in use. For the reasons described in this declaration, I believe that Mr. Simonson's posterior spinal disc replacement surgery approach is patentably distinct.

4. In the posterior approach to spinal disc replacement surgery, one makes the surgical incision(s) in the back of the patient. By contrast, in the anterior approach to spinal disc replacement surgery, one makes the surgical incision in the front of the patient, typically in the abdominal region. At first glance, one might suspect that the posterior approach would always be preferred since the spine is so much closer to the patient's back. This is not the case.

5. In the posterior approach, there are numerous bones and nerves blocking easy access to damaged spinal discs. The bones include the spinous processes, articulated processes, transverse processes, facet joints, lamina etc. Without cutting away these bones, there is only about 1 square centimeter of room to work on each side of the disc if the posterior approach is used. This working area can be slightly expanded if bone is cut away, but will still be quite small. Nonetheless, trying to expand the posterior approach working area, even slightly, runs the risk of causing permanent nerve injury. In view of the small accessible working area using a posterior approach, it is virtually impossible to cut away the entire damaged disc from

only one incision. Instead, one generally needs to make two incisions in order to approach the damaged disc from both the left and right sides.

6. By contrast, using the anterior approach, one can gain access to the entire spinal disc through a single incision in the region of the patient's abdomen. This greater area of access comes at a price, though. For lumbar spinal surgeries using the anterior approach, one needs to cut through and move aside extensive muscle and intestinal tissue in order to gain access to the damaged disc. In so doing, one runs the risk of inadvertently cutting the iliac vein and causing the patient to bleed extensively, possibly fatally.

7. Mr. Simonson's patent application pertains to the field of arthroplasty, or the use of medical devices to replace damaged disc tissue. Despite all the drawbacks of the anterior approach to disc replacement surgery, it was thought in the art of spinal surgery that the anterior approach was needed because the anterior approach would be the only way a device could be implanted to fully replace, both in size and function, a damaged disc.

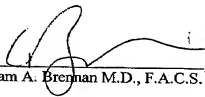
8. The reason Mr. Simonson's posterior approach to arthroplasty is patentably distinct from prior art anterior approaches is because Mr. Simonson has cast aside a number of common misconceptions in the field. For example, contrary to the conventional wisdom, Mr. Simonson recognizes in his invention that one does not need to use a single device which is approximately the same size as the damaged disc. Instead, Mr. Simonson uses two or more smaller devices which each can be inserted through very small working areas. According to conventional wisdom, Mr. Simonson's two or more smaller devices will not work because they inhibit axial rotation of the spine. Again, conventional wisdom is wrong in the case of damaged discs in the lumbar region because those discs are not intended by the body to axially rotate. In fact, in cases where disc replacement devices have been anteriorly implanted in the

lumbar region to allow full axial rotation, patient complications have arisen from excessive axial rotation.

9. For these reasons, Mr. Simonson's invention defies the conventional wisdom that a full size disc replacement device permitting axial rotation needs to be used for disc replacement surgery and the anterior method is the only choice available to surgeons for such a disc replacement device. Instead, Mr. Simonson has shown that, if two or more disc replacement devices are used which are small enough to fit through the very small posterior working areas, these devices can be successfully placed on each side of the medial plane defined by the spinous processes and thereby make the posterior approach a practical, if not preferable, alternative to conventional anterior disc replacement surgery.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: July 12, 2006



William A. Brennan M.D., F.A.C.S.